Sensus Healthcare, Inc
Nicolas Soro
QA/RA Manager
851 Broken Sound Parkway NW, Suite 215
BOCA RATON FL 33487

February 21, 2019

Re: K190255
Trade/Device Name: Sensus Healthcare TVM Balloon Applicator
Regulation Number: 21 CFR 892.5900
Regulation Name: X-Ray Radiation Therapy System
Regulatory Class: Class II
Product Code: JAD
Dated: February 6, 2019
Received: February 7, 2019

Dear Mr. Soro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190255

Device Name
TVM Balloon Applicator

Indications for Use *(Describe)*
The Sensus TVM Balloon Applicator is indicated for use with the Sensus IORT System to deliver intracavity or intraoperative brachytherapy wherever the physician chooses to deliver radiation treatment.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

510(k) SUMMARY

[As Required by 21 CFR 807.92(c)]

Submitter's Name & Address:	Sensus Healthcare 851 Broken Sound Parkway NW Suite 215 Boca Raton, FL 33487
Contact Person:	Kal Fishman, COO Telephone (561) 922-5808 Fax (561) 948-2071 kal@sensushealthcare.com
Date Summary Prepared:	February 6, 2019
Device Name:	Trade/Proprietary Name – TVM Balloon Applicator Common/Usual Name – Superficial X-ray Radiation Therapy System Classification Name – X-ray Radiation Therapy System (892.5900)
Predicate Device:	Xoft Axxent Balloon Applicator (K090914)
Reference Device:	N/A

Device Description:

The Sensus Healthcare TVM Balloon Applicator is a component of the Sensus Healthcare IORT system, which utilizes an X-ray source and does not employ radioactive isotopes. The TVM Balloon Applicator supports the Sensus Healthcare IORT System's ability to deliver intraoperative brachytherapy wherever the physician chooses to delivery radiation therapy. The Sensus Healthcare TVM Balloon Applicator is provided in one size (variable-volume balloon) to support the achievement of proper fit within the varying patient anatomies. The applicator is a single-use disposable device that is provided sterile. Product sterility is achieved through the use of Gamma radiation (reference ISO 11137-1).

Intended Use:

The Sensus Healthcare TVM Balloon Applicator is intended to support the delivery of high-dose-rate X-ray radiation in support for brachytherapy.

Indications for Use:

The Sensus TVM Balloon Applicator is indicated for use with the Sensus IORT System to deliver intracavity or intraoperative brachytherapy wherever the physician chooses to deliver radiation treatment.

Prescriptive Statement:

The TVM Balloon Applicator is intended for use by a physician and other specially-qualified individuals properly trained in the system's use and application.

Caution: Federal law restricts this device to sale by or on the order of a physician.

Technological Characteristics/Principles of Operation:

The TVM Balloon Applicator serves as an interface medium between the Sensus Healthcare IORT System and the patient's treated tissue surface. The TVM Balloon Applicator device is inserted post-surgical removal of the cancerous tumor through the surgical incision, or any other bodily cavity that allows access, and it is inflated to a desired volume in order to equally distribute the patient's tissue surface around the balloon in a pseudo-spherical geometry, which optimizes the radiation treatment planning and beam distribution in the treated tissue bed.

The TVM Balloon Applicator's volume is controlled by the inflation and deflation utilizing sterile saline solution through the Filling and Priming water lines attached to the balloon. The two syringes for inflation and deflation are connected to the water lines and flow system through the two-way and three-way stopcock valves, respectively. The saline bag that contains the saline medium solution is connected to the three-way stopcock valve and its flow is controlled by the Filling Syringe. The Priming Syringe is utilized to prime the balloon pre and during the balloon inflation/filling process and to deflate the balloon after the procedure is complete.

Once the balloon is positioned in the patient, at the designated treatment site, and secured to the patient's skin/exterior surface by the integrated Surgical Adhesive Membrane, the balloon is inflated by the Filling Syringe and its volume monitored by the operator utilizing a stand-alone ultrasound system. Once the TVM Balloon Applicator device is positioned, secured, and inflated to the required volume, the operators perform a stand-alone CT image of the nestled TVM Balloon Applicator device in the patient for image-guidance for the Treatment Planning System's (TPS) planning procedure. Once the treatment plan has been developed using the TPS, it is sent to the Sensus IORT System and the treatment is administrated to the patient. Once the

treatment delivery is complete, the balloon is deflated by the Priming Syringe, and the TVM Balloon Applicator device is extracted from the patient and disposed of in a bio-hazard-safe container. The patient is then sutured by the surgeon and the total procedure is complete.

The TVM Balloon Applicator device also incorporates three embedded Tantalum fiducial markers to assist with spatial orientation and registration of the TVM Balloon Applicator device in the patient. The fiducial markers are picked up by a stand-alone CT scan and provide the Treatment Planning System with the triangulating registration points of reference.

Non-Clinical Performance Testing:

Performance testing consisted of bench testing that has demonstrated that the performance of the TVM Balloon Applicator provided the same technical capabilities as the predicate device. Performance testing was executed to validate the operational characteristics associated with the TVM Balloon Applicator.

TEST REPORT	TEST
6-2-6684-0000	System Level Verification Test
6-2-6422-0000	System Level Validation Test
TVM-PPQ-001	Pull Testing
TVM-PPQ-002	Decay Testing
TVM-PPQ-003	Burst Testing

Non-clinical Safety Tests:

The Sensus Healthcare TVM Balloon Applicator has been designed and constructed to meet the following electrical and mechanical safety standards:

- **ISO 11137-1** - Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

- **ISO 11607-1** - Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems
- **ISO 11607-2**- Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
- **ISO 10993-1** - Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
- **ISO 10993-5** - Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- **ISO 10993-10** - Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
- **ISO 10993**-11 – Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity

TEST STANDARD	TEST	REPORT
ISO 10993-5	Cytotoxicity	18-02594-G2
ISO 10993-10	Intracutaneous Injection	18-02594-G3
ISO 10993	Skin Sensitization	18-02594-G1
ISO 10993-11	Acute Systemic Toxicity	18-04745-G1
USP Chapter <151>	Pyrogenicity Test	F18-1619-00 F18-1620-00 F18-1621-00
ISO 11137	Gamma Sterilization	F18-1038-00
ISO 11607	Package Validation	TVM-PV-001 F18-0931-00 F18-1039-00 F18-1040-00
ASTM D4169-16	Transit Testing	115-18-2759A